Indication

VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with VILTEPSO. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Important Safety Information

Warnings and Precautions: Kidney toxicity was observed in animals who received viltolarsen. Although kidney toxicity was not observed in the clinical studies with VILTEPSO, the clinical experience with VILTEPSO is limited, and kidney toxicity, including potentially fatal glomerulonephritis, has been observed after administration of some antisense oligonucleotides. Kidney function should be monitored in patients taking VILTEPSO. Serum creatinine may not be a reliable measure of kidney function in DMD patients.

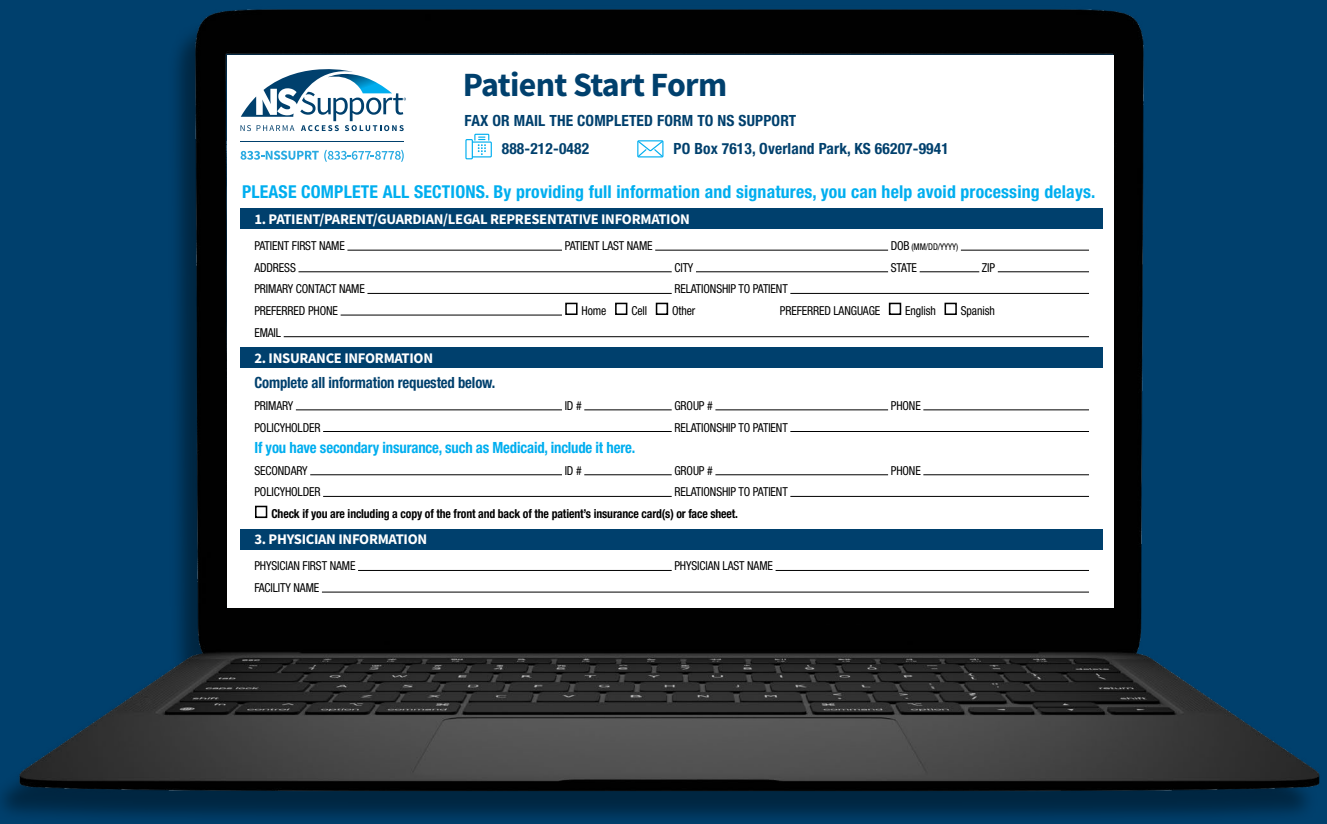
Please see Important Safety Information throughout. For additional information about VILTEPSO, see accompanying full Prescribing Information.

How to Initiate Treatment

DOWNLOAD THE PATIENT START FORM AT VILTEPSO.COM

CONNECT WITH NS SUPPORT — **833-NSSUPRT (833-677-8778)**

Monday–Friday, 8 AM–8 PM ET



Important Safety Information (continued)

Serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio should be measured before starting VILTEPSO. Consider also measuring glomerular filtration rate before starting VILTEPSO. During treatment, monitor urine dipstick every month, and serum cystatin C and urine protein-to-creatinine ratio every three months.

Dosing

VILTEPSO is given as an 80-mg/kg weekly intravenous (IV) infusion.[1] VILTEPSO can be administered using either a peripheral or central venous catheter.

Calculate the dose based on the patient's weight and the recommended dose of 80 mg/kg	**For example,** a 35-kg child will need 2800 mg of VILTEPSO (35 kg × 80 mg/kg)
80 mg/kg × patient's weight (in kg) = total dose of VILTEPSO (in mg) needed each week	

Calculate the volume needed based on the concentration in a single-dose 50-mg/mL vial	**For example,** a 35-kg child will need 56 mL of VILTEPSO (35 kg × 80 mg/kg ÷ 50 mg/mL)
[80 mg/kg × patient's weight in kg] ÷ 50 mg/mL = volume of VILTEPSO (in mL) needed	

Note: If the volume of required VILTEPSO is less than 100 mL, dilution in 0.9% sodium chloride for injection, USP, is required such that the total volume in the infusion bag is 100 mL.

PLEASE SEE THE WEEKLY DOSING CHARTS FOR ODD BODY WEIGHTS-BASED CALCULATIONS ON THE NEXT PAGE ▶

USP=United States Pharmacopeia.

Please see Important Safety Information throughout. For additional information about VILTEPSO, see accompanying full Prescribing Information.

Viltepso®
(viltolarsen) injection

Weekly Dosing Chart[1]

Only odd kg body weight provided for illustrative purposes.

Body weight (kg)	Body weight (lb)	Total VILTEPSO dose (mg)	Calculated number of vials required (vial)	Whole number of vials required (vial)	Volume of saline retained in infusion bag* (mL)	Volume of VILTEPSO injected into infusion bag (mL)	Total volume of VILTEPSO solution in infusion bag (mL)
15.0	33.0	1200	4.8	5	76.0	24.0	100.0
17.0	37.4	1360	5.4	6	72.8	27.2	100.0
19.0	41.8	1520	6.1	7	69.6	30.4	100.0
21.0	46.2	1680	6.7	7	66.4	33.6	100.0
23.0	50.6	1840	7.4	8	63.2	36.8	100.0
25.0	55.0	2000	8.0	8	60.0	40.0	100.0
27.0	59.4	2160	8.6	9	56.8	43.2	100.0
29.0	63.8	2320	9.3	10	53.6	46.4	100.0
31.0	68.2	2480	9.9	10	50.4	49.6	100.0
33.0	72.6	2640	10.6	11	47.2	52.8	100.0
35.0	77.0	2800	11.2	12	44.0	56.0	100.0
37.0	81.4	2960	11.8	12	40.8	59.2	100.0
39.0	85.8	3120	12.5	13	37.6	62.4	100.0
41.0	90.2	3280	13.1	14	34.4	65.6	100.0
43.0	94.6	3440	13.8	14	31.2	68.8	100.0
45.0	99.0	3600	14.4	15	28.0	72.0	100.0
47.0	103.4	3760	15.0†	16	24.8	75.2	100.0
49.0	107.8	3920	15.7	16	21.6	78.4	100.0
51.0	112.2	4080	16.3	17	18.4	81.6	100.0
53.0	116.6	4240	17.0	17	15.2	84.8	100.0
55.0	121.0	4400	17.6	18	12.0	88.0	100.0
57.0	125.4	4560	18.2	19	8.8	91.2	100.0
59.0	129.8	4720	18.9	19	5.6	94.4	100.0
61.0	134.2	4880	19.5	20	2.4	97.6	100.0
63.0	138.6	5040	20.2	21	–	100.8	100.8
65.0	143.0	5200	20.8	21	–	104.0	104.0
67.0	147.4	5360	21.4	22	–	107.2	107.2
69.0	151.8	5520	22.1	23	–	110.4	110.4

*If volume of VILTEPSO required is <100 mL, dilution in 0.9% sodium chloride for injection, USP, is required such that the total volume in the infusion bag is 100 mL. If the volume of VILTEPSO to be infused is ≥100 mL, dilution is not required.

†The actual number of calculated vials required is 15.04.

Preparation and Administration

VILTEPSO is supplied in single-dose (250 mg/5 mL) vials in a clear, colorless, preservative-free solution[1]

- Visually inspect each vial. Do not use if the solution in the vials is discolored or particulate matter is present.
- Allow the vials to warm to room temperature.
- Mix the contents gently by inverting 2 to 3 times. Do not shake.

Prepare the VILTEPSO solution for infusion using aseptic technique[1]

If **less than 100 mL** of VILTEPSO is required:

1. Withdraw the calculated volume of VILTEPSO from the appropriate number of vials.
2. From a 100-mL infusion bag of 0.9% sodium chloride for injection, USP, withdraw a volume that is equivalent to the calculated volume of VILTEPSO.
3. Inject VILTEPSO into the infusion bag.
4. Visually inspect the infusion bag for particulates.
5. Gently invert the infusion bag to ensure equal distribution. Do not shake.
6. Discard unused VILTEPSO.

If **100 mL or more** of VILTEPSO is required, no additional dilution with 0.9% sodium chloride for injection, USP, is required, and the required amount of VILTEPSO should be placed into an empty infusion bag. Visually inspect the infusion bag for particulates. Gently invert the infusion bag.

Selecting a comfortable needle size may help reduce injection discomfort[2,3]

Preparation and Administration

It should take 60 minutes to complete IV infusion of VILTEPSO[1]

- Begin infusion as soon as possible—no more than 5 hours after preparation—and complete within 6 hours of preparation if diluted solution is stored at 20° C to 26° C (68° F to 79° F)
- Do not mix other medications with VILTEPSO or infuse other medications concomitantly via the same IV access line
- Flush the IV access line with 0.9% sodium chloride for injection, USP, after infusion

If injection site reaction or post-infusion low-grade fever occurs, patients may be managed on-site or at home with appropriate management techniques, including[4]:

- Over-the-counter pain relievers
- Antihistamines
- Antipyretics
- Cold compresses

Important Safety Information (continued)

Urine should be free of excreted VILTEPSO for monitoring of urine protein. Obtain urine either prior to VILTEPSO infusion, or at least 48 hours after the most recent infusion. Alternatively, use a laboratory test that does not use the reagent pyrogallol red, which has the potential to generate a false positive result due to cross reaction with any VILTEPSO in the urine. If a persistent increase in serum cystatin C or proteinuria is detected, refer to a pediatric nephrologist for further evaluation.

Please see Important Safety Information throughout. For additional information about VILTEPSO, see accompanying full Prescribing Information.

Viltepso®
(viltolarsen) injection

VILTEPSO offers a choice of treatment location — at home or at a treatment center

VILTEPSO is given as an 80-mg/kg weekly **IV infusion**[1]

The **appropriate dose** of VILTEPSO is calculated based upon **patient weight**, at a recommended weekly dosage of 80 mg/kg[1]

VILTEPSO is infused for **60 minutes** by a healthcare professional, at home or at a treatment center[1]

DOWNLOAD THE PATIENT START FORM AT VILTEPSO.COM TO GET YOUR PATIENTS INITIATED ON TREATMENT

Indication

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Important Safety Information (continued)

Adverse Reactions: The most common adverse reactions include upper respiratory tract infection, injection site reaction, cough, and pyrexia.

Please see Important Safety Information throughout. For more information about VILTEPSO, see accompanying full Prescribing Information.

References: 1. Viltepso [prescribing information]. Paramus, NJ: NS Pharma, Inc.; 2021. **2.** Gill HS, Prausnitz MR. Does needle size matter? *J Diabetes Sci Technol*. 2007;1(5):725-729. **3.** Aronson R. The role of comfort and discomfort in insulin therapy. *Diabetes Technol Ther*. 2012;14(8):741-747. **4.** Cole B. Injection-site reactions and how to manage them. *Pharmacy Times*. 2019;1(5):1-11.

NS Pharma

Viltepso®
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With the help of VILTEPSO, Mason and his family may have more opportunities to create meaningful moments.

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